SEP 15 2009

K092134
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510k Summary of Safety & Effectiveness

This summary of 510k Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Date of Submission:	(updated 8/04/09)
Submitter/Mfg:	StatRad, LLC
Company Contact:	Joe Moock, CEO
Preparer/510k Contact:	Linda J. Moore, Regulatory Consultant, 408-504-0565 lindajm@aol.com
Device Name Common/usual name: Proprietary Name:	Picture Archiving & Communications System (PACS) Medical Imaging Processing/Teleradiology System StatPacs™

Predicate device(s):	Virtual Radiologic Corporation 11995 Singletree Lane Minneapolis, MN 55344	vRad PACS K090649
	Mercury Computer Systems Inc. 199 Riverneck Rd. Chelmsford, MA 01824-2820	VISAGE PACS/CS K062490
	VISAGE IMAGING, INC 1815 ASTON AVENUE, SUITE 107 CARLSBAD, CALIFORNIA, 92008	VISAGE PACS/CS K082269

Description/Intended use:

The StatPacs™ is a software based PACS product, intended to be used by radiologists, technologists and clinicians, to operate on specified off the shelf hardware (OTS) that will provide teleradiology and PACS solution for hospitals/clinics and remote site use. The StatPacs™ software will transmit, receive, display, and store 2D/3D images for clinical evaluation and diagnosis.

Networked gateways, including LAN/WAN through DICOM and other industry standards allow StatPacs™ to interface to all modalities including but not limited to, CT, MRI, Ultrasound (US), CR, DR, Nuclear Medicine (NM), PET, digitized radiographic films and all administration systems. StatRad, LLC provides and installs off the shelf hardware including a hospital and central server, at client hospitals and off site facilities to ensure a safe, secured, private network for image transmission via the internet. No equipment is installed in the patient environment. Additionally, VPN's and other encryption methodology are utilized and allow rapid transmission of images. Image compression and encryption adhere to standard industry protocol. StatView™ with the Exam Manager™ application is a primary user interface for processing of medical images for primary image diagnosis. StatPacs™, is not to be used for mammography imaging.

Technical Characteristics:

This is a medical imaging software device that is used with OTS computer hardware in a picture archiving and communications system user environment. The device does not contact the patient, nor does it control any life sustaining devices. The technical characteristics are similar in design, technical requirements and intended use to predicate devices.

Substantial Equivalence Summary

The StatPacs™ is substantially equivalent in design, technical requirements, and intended use to diagnostic radiological workstations, PACS and image management systems as substantiated in the feature comparison. The predicate device comparison clearly demonstrates that StatPacs™ is substantially equivalent in all areas such as functionality, user/software features, OTS hardware components and connectivity.

Conclusions:

Based on the information provided in this premarket notification submission, StatPacs™ is substantially equivalent to predicate devices and raises no new issues of safety or effectiveness from its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 15 2009

StatRad LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K092134
Trade/Device Name: StatPacs™ Picture Archiving and Communications Systems (PACS) Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 1, 2009
Received: September 2, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement (Section B2)

510k # K092134

Device Name:

StatPacs™ Picture Archiving and Communications Systems (PACS) Software

Indications for Use

The StatPacs™ is a software based PACS product intended to be used by radiologists, technologists and clinicians, to operate on specified off the shelf hardware that will provide a teleradiology and PACS solution for hospital and remote site use. The StatPacs™ software will transmit, receive, display, and store 2D/3D images for clinical evaluation and diagnosis by way of industry standard networked gateways including VPNs, and LAN/WAN through DICOM allowing StatPacs™ to interface to all modalities including but not limited to, CT, MRI, Ultrasound (US), CR, DR, Nuclear Medicine (NM), PET, digitized radiographic films and all administration systems. StatView™ with the Exam Manager™ application, is a primary user interface for processing of medical images for primary image diagnosis. Image compression and encryption adhere to standard industry protocol. StatPacs™, is not to be used for mammography imaging.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence or CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092134